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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,660	08/22/2000	Jonathan Schneck	01107.00042	9271

7590 03/26/2002

Banner & Witcoff Ltd  
1001 G Street NW  
Washington, DC 20001-4597

[REDACTED] EXAMINER

BANSAL, GEETHA P

ART UNIT	PAPER NUMBER
1642	9

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <u>09/642,660</u>	Applicant(s) <u>Schneck et al</u>
Examiner <u>Gretta Bansal</u>	Group Art Unit <u>1642</u>

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3 - MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on 1/10/02

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

Claim(s) 28-32, 51-60 is/are pending in the application.

Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 28-32, 51-60 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). 1 sheet  Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

## Office Action Summary

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**DETAILED ACTION**

1. Applicant's amendment filed 1/10/02 (Paper No:7/B) is acknowledged. Accordingly, claims 1-27, 33-50 are canceled without prejudice, and claims 51-60 added.

Claims 28-32, 51-60 are pending.

2. Applicant's election of Group III (claims 28-32) in Paper No. 7/B is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Newly added claims have been reviewed and added to the elected Group.

Claims 28-32, 51-60 are being examined.

3. The abstract of the disclosure is objected to because it is not drawn to the subject matter claimed. Correction is required. See MPEP § 608.01(b). It is suggested that addition of the elected invention top the existing abstract may be adequate to satisfy inclusion of the elected invention in the instant Abstract.

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

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6. Claims 28-32, 51-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

b1c A. Claim 32, 56-58 are unclear because they lack antecedent basis for "antigenic peptides of the population".

7 A. Claims 56-57 are ambiguous since the metes and bound of "actively bound" and "passively bound" are not clear.

01c C. Claim 60 is indefinite in that it is not clear what the metes and bound of "molecule which stimulates an immune response".

D. *The bridging sentence on pg 22-23 is unclear. Drawn*

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 28-32, 51-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a composition comprising a cell to which is bound a molecular complex, wherein the molecular complex comprises at least 4 fusion proteins, and wherein two first fusion proteins each comprise an immunoglobulin heavy chain and an extracellular domain of a first transmembrane protein, and two second fusion proteins each comprise an immunoglobulin light chain and an extracellular domain of a second transmembrane protein, such that the first and second fusion proteins associate to form a molecular complex having two ligand binding sites. The specification teaches the making of a molecular complex as described above. The specification further contemplates the use of the molecular complexes to identify peptides that

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would bind to the TCR or to identify antigen specific T cells, and to identify peptide/MHC complexes (pages 20-21). The specification also contemplates the molecular complexes to be bound to the surface of a cell such as a dendritic cell by introducing amino acid sequence into the fusion peptides of the complex to anchor the complex on the cell surface (page 22). [However, there is no teaching in the specification, nor any guidance provided as to how to make a composition comprising a cell to which the said molecular complex is bound. The specification does not provide a clear teaching as to how and in what defined form and manner such a binding is achieved. Alternatively said, there is no guidance provided in the specification as to what cognate ligand binding specificity provided by the ligand binding sites is needed to bind to a cell, and what type of cell is intended. Further, it is not clear if the claims intend for the molecular complex to be bound to any cell via the ligand binding sites or via other parts of the complex such as the various immunoglobulin domains. There are no working examples provided that could enable of skill in the art to determine exactly where on the complex the extra aminoacid residues (for the purposes of anchoring the complex to the surface of the cell as disclosed on page 22) should be placed such that the complex when bound to the cell can function as Applicant intended, but the functional intent is not disclosed either. Moreover, it is not clear from the specification [what the purpose and use for a composition comprising a cell to which is bound the molecular complex of the invention is.] Therefore one of skill in the art would be forced into undue experimentation to practice the claimed invention, because the specification provides no clear guidance or teaching as to how to bind or anchor the molecular complex to the surface of a cell, i.e. what portion or domain of the complex is bound to the cell surface, what type of cell other than dendritic cell is intended, and if the complex is integrated into the membrane of the cell via defined amino acids- how that is achieved. For the reasons stated above it would be undue experimentation for one of skill in the art to practice the claimed invention.

9. No claim is allowed. However, the claims have been found to be free of the prior art.

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10. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays, and alternate Wednesdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308-3995.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 15, 2002.

  
GEETHA P. BANSAL  
PRIMARY EXAMINER